SECTION 5
510(k) SUMMARY

510(k) Notification K 112906

GENERAL INFORMATION

Applicant:

Total Joint Orthopedics, Inc.
1567 E. Stratford Avenue
Salt Lake City, UT 84106
Phone: 801-486-6070
Fax: 801-486-6117

Contact Person:

Heather Lake
Sr. Manager, Regulatory Affairs
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085
Phone: 408-400-0856
Fax: 408-400-0865

Date Prepared: September 30, 2011

DEVICE INFORMATION

The Klassic™ Knee System is a cemented total knee joint replacement system comprised of modular components with varying sizes available for each component.

Trade Name:

Klassic™ Knee System

Generic/Common Name:

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Classification:

21 CFR§888.3560, Class II

Product Code:

JWH

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PREDICATE DEVICE(S)

- Ortho Development Corporation, Balanced Knee™ System (K994370)
- Ortho Development Corporation, Balanced Knee™ System Ultracongruent Tibial Insert (K090705)
- Intermedics Orthopedics, Natural-Knee® II System (K936159)
- OMNI Life Science, Inc., Apex Knee™ System (K060192)
- Intermedics Orthopedics, Natural-Knee®/Apollo™ Knee (K925242, K935523)
- Howmedica Corp., Kinemax Plus Total Knee System (K910500)

INDICATIONS FOR USE

The Klassic™ Knee System is intended for prosthetic replacement with the use of bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Correctable varus-valgus deformity and moderate flexion contracture
- Revision of a previously failed knee arthroplasty
- Patients who require a total knee replacement

PRODUCT DESCRIPTION

The Klassic™ Knee System consists of two categories of devices: an implantable knee prosthesis and the various instruments needed to perform the surgery and implant the femoral, tibial and patellar components. The Klassic™ Knee System allows for simple surgical use and addresses the needs of a wide patient population. The System also has streamlined instrumentation.

The Klassic™ Knee System is a cemented total knee joint replacement system intended for use in primary knee surgery. The System is a semiconstrained design and both the medial and lateral collateral ligaments must be intact. The Klassic™ Knee System utilizes a symmetrical design, eliminating the need for left/right orientations. The patellofemorotibial prosthesis includes a metal femoral component, a tibial component consisting of a polyethylene tibial bearing fixed to a metal tibial baseplate, a polyethylene patellar component, a polyethylene dome extension, and a metal tibial insert set screw. The implantable components are provided sterile and are intended for single-use only in a single patient.

The Cobalt Chromium alloy (CoCr) femur has a symmetric design and is available in six sizes for cemented application to accommodate replacement of either left or right knees.

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The Titanium alloy tibial baseplate has a symmetric design and is available in six sizes for cemented application. The tibial baseplate has a modular design to assemble with the tibial insert with a snap-in locking mechanism that is secured with the Titanium alloy tibial insert set screw. The System includes two types of tibial inserts which can be used in cruciate retaining and cruciate sacrificing procedures. Both types of tibial inserts have a symmetric design, are composed of ultrahigh molecular weight polyethylene (UHMWPE) and are available in six sizes and four thicknesses (10-16mm). The System also includes a patella composed of UHMWPE which is available in four sizes. Additionally, the System includes a dome extension composed of UHMWPE that connects to the bottom of the tibial baseplate and is available in one size. The UHMWPE material has been utilized in previously cleared devices.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Klassic™ Knee System are similar to the predicate devices. Performance data were provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the Klassic™ Knee System are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic™ Knee System is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Extensive bench testing was conducted on the Klassic™ Knee System to evaluate the performance of the device and to support a determination of substantial equivalence to the predicate devices. Non-clinical testing assessed the following aspects of the device:

- Fatigue
- Disassembly
- Stability
- Contact area and stress distributions
- Range of motion
- Biocompatibility
- Sterilization and cleaning validations
- Packaging and shelf life

All testing was performed in accordance with recognized standards. Results confirm that all components of the Klassic™ Knee System exhibit the appropriate characteristics for total knee joint replacement, and are substantially equivalent to the predicate devices.

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CONCLUSION

The results of the non-clinical testing verify that the Klassic™ Knee System functions as intended and exhibits the appropriate characteristics for total knee joint replacement. The Klassic™ Knee System is substantially equivalent to the predicate devices in terms of technological characteristics, intended use and performance.

SUMMARY

The Klassic™ Knee System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 1 2012

Total Joint Orthopedics, Inc.
% Ms. Heather Lake
Regulatory Consultant for Total Joint Orthopedics, Inc.
Experien Group, LLC
755 N. Mathilda Avenue
Sunnyvale, California 94085

Re: K112906
Trade/Device Name: Klassic Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: January 19, 2012
Received: January 20, 2012

Dear Ms. Lake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Lim DSP

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112906

Device Name: Klassic™ Knee System

Indications For Use:

The Klassic™ Knee System is intended for prosthetic replacement with the use of bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
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Prescription Use X And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Surgical, Orthopedic,
and Restorative Devices

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